



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/822,037

04/08/2004

Mark C. Bates

33769-1013

9083

35023

7590

04/29/2008

LUCE, FORWARD, HAMILTON & SCRIPPS LLP  
11988 EL CAMINO REAL, SUITE 200  
SAN DIEGO, CA 92130

EXAMINER

BOUCHELLE, LAURA A

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

04/29/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/822,037	<b>Applicant(s)</b> BATES, MARK C.	
	<b>Examiner</b> LAURA A. BOUCHELLE	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 18-60 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18-60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/7/07</u> .  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Response to Amendment***

***Claim Rejections - 35 USC § 102***

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 18-31, 35-56, 59, 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Humes (US 5911704). Humes discloses an implantable device and method comprising the steps of providing an apparatus having an anchor 20 expandable from a delivery configuration to a deployed configuration, and a material 10 adapted to elute a bioactive substance, disposing the anchor in the delivery position, advancing the distal end of a delivery sheath to the delivery site, expanding the anchor to engage the interior wall of a vessel, eluting a bioactive substance, and removing the anchor (Col. 16, line 15 – col. 17, line 20). The eluting material may be filaments, which are elongated members adapted for multiple turns.
3. Humes discloses that the anchor 20 comprises a head 26, barbed filaments 22 biased radially outwardly attached at one end to the head. The anchor comprises an interlocking receptacle for receiving an interlocking element 40 of the capsule 10. See Fig. 6A. The reservoir is an osmotic pump (Col. 9, lines 37-42). The reservoir comprises a biocompatible polymeric semi-permeable membrane defining pores of size sufficient to permit diffusion of preselected drug therethrough over a preselected period of time (Col. 10, lines 16-24, Col. 8, lines 19-22). The drug may be a coagulation factor (Col. 2, lines 20-25).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 32-33, 57, 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Humes in view of Leong (WO 95/2618). Claims 32, 33 differ from Humes in calling for the eluting material to include a spongy material or a foam. Leong teaches the use of foam to elute drugs after implantation into the body for long term, non-invasive delivery of the drug to a specific area. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Humes to include a drug eluting foam as taught by Leong to provide long term drug delivery to a specific area within the body.

6. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Humes in view of Leong. Claim 34 differs from the teachings above in calling for the spongy member to be steel wool. At the time the invention was made, it would have been an obvious matter of design choice to form the drug eluting member of steel wool. Applicant has not disclosed that having steel wool serves any advantage or particular purpose or solves a stated problem. Furthermore, one of ordinary skill would expect Humes and applicant's invention to perform equally well with either a pellet, filaments, foam or steel wool because each are known drug eluting substances. Therefore, it would have been prima facie obvious to modify the device of Humes in view of Leong to obtain the invention as specified in claim 34 because such a modification would have

Art Unit: 3763

been considered a mere design consideration which fails to patentably distinguish over the prior art.

***Response to Arguments***

7. Applicant's arguments filed 11/10/07 have been fully considered but they are not persuasive. Applicant argues that Humes fails to teach an eluting substance, and discloses only diffusion. The examiner argues that diffusion is a form of elution. The definition of elution is the removal of absorbed material. In the instant application, the absorbed material is dispersed into the environment (i.e. the blood stream). Diffusion is defined as distribution or spilling out of contained material. Humes teaches that the contained material is diffused into the passing blood stream. It is clear that in the instant case, diffusion and elution are the same process.

***Conclusion***

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 3763

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA A. BOUCHELLE whose telephone number is (571)272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura A Bouchelle  
Examiner  
Art Unit 3763

/L. A. B./  
Examiner, Art Unit 3763

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763